REMARKS/ARGUMENTS

This is in response to the final Office Action mailed April 17, 2003, in the above-referenced application. Entry of the foregoing amendments is respectfully requested. The amendments do not present new issues for consideration by the Examiner, or, alternatively, place the claims in better form for appeal. The rejections of record are addressed below.

Claim 2 is rejected as indefinite. Claim 2 is amended as suggested by the Examiner to refer to "amino acid residues," in place of "amino acids." To provide consistency in the claims, Claims 1 and 3-4 are similarly amended. Applicants accordingly request withdrawal of this rejection.

Claims 1-6 are rejected under 35 USC Section 102(b) as anticipated by Simon et al. Applicants offer the following comments.

As explained in Applicants' prior response, naturally occurring human filaggrin does not consist of a single polypeptide. Rather, naturally occurring human filaggrin includes a population of polypeptides of different sequences since it is synthesized as a large precursor (profilaggrin) comprising filaggrin units displaying important variations between them.

In contrast, when a recombinant or synthetic filaggrin or filaggrin fragment is prepared, it is obtained from the sequence of an individual filaggrin unit. This results in a population of polypeptides having the same sequence.

The artificial antigen of Claim 1 is derived from a single filaggrin unit. Claim 1 is amended to clarify this aspect of the invention by stating that antigen consists of a recombinant or synthetic polypeptide derived from any one of the filaggrin variants represented by SEQ ID NO: 7. As a result, the claimed invention is a homogenous preparation of polypeptides having the same sequence and does not include a mixture of polypeptides of different sequences.

The Examiner refers to page 436, column 2, 1st paragraph, and page 434, column 2, 2nd paragraph, of Simon et al. as teaching a citrulline-containing, modified synthetic filaggrin peptide. The cited sections of Simon et al., however, refer to different types of peptides.

In particular, page 436, column 2, 1st paragraph of Simon et al. refers to a citrulline-containing epitope present only on the "post-translationally modified filaggrin" (emphasis

added). This corresponds to filaggrin purified from human epidermis, as discussed in the first paragraph in the "Materials and Methods" section of the article.

This preparation is used in the immunoblotting of Figures 3 and 4. Figure 4 (blotting after 2 dimensional gel electrophoresis) illustrates that the preparation displays the comma-shaped migration typical of filaggrin extracted from human epidermis. This in turn reflects the heterogeneity of such a preparation, in contrast to the homogenous nature of the claimed invention.

In contrast, page 434, column 2, 2nd paragraph, of Simon et al. is directed to an alternative preparation. Specifically, in contrast to the peptides derived from human epidermis referenced on page 436, page 434 of Simon et al. refers to synthetic peptides derived from the consensus sequence of human filaggrin. These peptides represent fragments of the "native," i.e., not post translationally modified sequence of filaggrin. These peptides are not citrullinated. Not only are the peptides not citrullinated; Simon et al. nowhere teaches or suggests treating the synthetic peptides to citrullinate the same.

Thus, the Simon e al. article discusses either peptides derived from human epidermis that are not homogenous or synthetic peptides that are not citrullinated. Nowhere do Simon et al. teach or suggest synthetic peptides as recited in claim 1 which are homogenous (derived from one of the filaggrin variants of SEQ ID NO:7) and also citrullinated. Not only do Simon et al. not teach the claimed peptides; there is no suggestion or motivation in the cited art to modify the peptides taught therein to provide the claimed invention. Accordingly Applicants submit that the claimed invention is patentable and respectfully request withdrawal of this rejection.

The rejections of record having been addressed in full in the foregoing, it is respectfully submitted that this application is now in condition for allowance, which action is respectfully solicited. Should the Examiner has any questions regarding the foregoing it is respectfully requested that she contact the undersigned at her convenience.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Melissa B. Pendleton

Melissa B. Pendleton
Registration No. 35,459

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111
CLT01/4601302v1

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. 703-872-9307 on the date shown below.

Grace R. Rippy

July 17, 2003
Date